IN UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO KRISTIN JACOBSON
CASE NO. 2:17-cv-02046

MDL No. 2327

PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

INTRODUCTION

Defendants' Motion for Summary Judgment challenges nearly all of Plaintiffs' claims.[1] Def. Mem. Supp. Mtn. Summ. J., October 16, 2018, Dkt. 30, ("Def. Mem."). Because questions of fact preclude summary judgment, Plaintiffs' failure to warn, design defect, manufacturing defect, negligence, negligent misrepresentation, negligent infliction of emotional distress, gross negligence, fraud, fraudulent concealment, UCL, and unjust enrichment claims survive summary judgment.

STATEMENT OF MATERIAL FACTS

Plaintiff is a citizen of the State of California, and all of Ms. Jacobson's treatment, as alleged in her Short Form Complaint, occurred in the State of California. (*See* Dkt. 1 at 4.) Kristin Jacobson began experiencing symptoms of stress urinary incontinence ("SUI") in 1999.

[1] Defendants do not move for summary judgment on Plaintiffs' Negligence Claims (other than as to negligent manufacturing) (Count I), Loss of Consortium (Count XVI), and Punitive Damages (Count XVII). Plaintiffs concede their Breach of Express and Implied Warranty Claims, Constructive Fraud, Strict Liability—Defective Product (Count IV), and claims under the CLRA.

(*See* Ex. B, Deposition of Kristin Jacobson, 66:17-23.) Despite doing Kegel exercises at her physician's instructions, her symptoms slowly worsened over time. (*See* Ex. A, Kristin Jacobson Medical Records, LCHB-KLJ-000611.) The leakage was inconvenient and interfered with her ability to exercise. (*See* Ex. B 68:3-8.) Due to more pressing concerns in her life, she did not seek treatment for SUI, until approximately 2012. (*See* Ex. A LCHB-KLJ-000611.)

Ms. Jacobson presented to Dr. Cronbach, her gynecologist, seeking to finally treat her SUI because she could no longer run long distances and play volleyball with her daughter. (*See* Ex. A LCHB-KLJ-000611.) Dr. Cronbach offered several options for conservative treatment, including a pessary and incontinence dish, which Ms. Jacobson tried without improvement. (*See* Ex. A LCHB-KLJ-000668, LCHB-KLJ-000697.) Dr. Cronbach then offered definitive treatment with a mid-urethral TVT sling to "hold up her urethra." (*See* Ex. A LCHB-KLJ-000697; Ex. B 78:19-25.) At the time, Dr. Cronbach noted that Ms. Jacobson was "sexually active without discomfort." (*See* Ex. A LCHB-KLJ-000611.)

In the course of their informed consent discussion regarding risks and benefits of the TVT procedure, Dr. Cronbach did not discuss dyspareunia or painful intercourse, or significant limitations on her activity as potential risks of implantation of the Sling. (*See* Ex. B 77:13-78:6, 79:21-82:7; Ex. A LCHB-KLJ-000697-000700, LCHB-KLJ-000775-000777; Ex. M, Kristin Jacobson Amended Plaintiff Fact Sheet, 5.) *See also* Ex. A LCHB-KLJ-000033 (reviewing risks of urinary retention and urge incontinence). Ms. Jacobson signed a consent form for her mid-urethral sling TVT procedure, stating that Dr. Cronbach explained to her the risks following benefits, alternatives, and dangers: "Benefit: treat stress incontinence and improve quality of life. Expected success rate of 90%. Alternatives: pessary use or no treatment. Risks: pain, bleeding, infection, risk of failure of the procedure (tape too loose), risk of urinary retention (tape

too tight) which might require self-catheterization for a period of time and/or additional procedures to correct. Risk of bladder perforation which is relatively common (~10%) and typically requires a catheter for several days. Risk of new onset bladder irritability/urgency which may require medication. Over many years, there is a risk of recurrent symptoms and possible need for repeat surgery." (*See* Ex. A LCHB-KLJ-000775-000777.)

On December 11, 2012, at Kaiser Foundation Hospital, Ms. Jacobson was implanted with the Ethicon Gynecare TVT by Dr. Emily Cronbach to treat her SUI. (*See* Ex. A LCHB-KLJ-000727-000728.)

Ms. Jacobson first began to have problems with the Gynecare TVT device approximately four years after it was implanted. (*See* Ex. B 99:6-12.) She began to feel rubbing, discomfort, and spotting, as well as "intermittent pain" during athletic activities, especially a "sharp kind of tearing kind of pain" during abdominal exercise. (*See* Ex. B 100:4-21.) She was limited in her ability to engage in high impact activities, due to pain and recurrent leakage, and also began to have pain during intercourse. (*See* Ex. B 113:15-115:21.) For these problems, she saw Dr. Marlene Freeman, an OB / GYN at Sutter Health. On December 5, 2016, Dr. Freeman diagnosed Ms. Jacobson with vaginal erosion due to surgical mesh, SUI, and vaginal atrophy. (*See* Ex. A LCHB-KLJ-000969.) Dr. Freeman also noted that the mesh may have migrated as it appeared to be located more on the distal urethra rather than the mid urethra. (*See* Ex. A LCHB-KLJ-000969.) To address Ms. Jacobson's vaginal erosion of her urethral sling, Dr. Freeman performed a mesh excision and cystourethroscopy on December 14, 2016. (*See* Ex. A LCHB-KLJ-000974-000976.) During the same operation, Dr. Freeman also placed the Coloplast Aris sling, a transobturator mid-urethral sling. (*See* Ex. A LCHB-KLJ-000974-000976.) While Ms. Jacobson preferred not to have another polypropylene mesh implanted, Dr. Freeman told her

that without another sling, she would be totally incontinent, leaving her practically no choice. (*See* Ex. B 102:1-103:23.) Following this operation, Ms. Jacobson had an appointment with Dr. Freeman on December 30, 2016, where she reported that she was feeling well but still had some bleeding, urinary leakage, and minimal pain. (*See* Ex. A LCHB-KLJ-000977.) Following her surgery with Dr. Freeman in 2016, Ms. Jacobson was able to resume intercourse with her husband without pain. (*See* Ex. B 113:15-116:4.) She no longer suffers from the same debilitating pain and can do more activities around the house. (*See* Ex. B 113:15-116:4.)

SUMMARY JUDGMENT STANDARD

Summary judgment may be granted only if there is no genuine issue as to any material question of fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). As the non-moving party, Plaintiff is entitled "to have the credibility of [their] evidence as forecast assumed, [her] version of all that is in dispute accepted, all internal conflicts in it resolved favorably to [her], the most favorable of possible alternative inferences from it drawn in [her] behalf; and finally, to be given the benefit of all favorable legal theories invoked by the evidence so considered." *Charbonnages de France v. Smith*, 597 F.2d 406, 414 (4th Cir. 1979); *Trull v. Smolka*, 411 F. App'x 651, 658 (4th Cir. 2011). Summary judgment should be denied "'even where there is no dispute as to the evidentiary facts but only as to the conclusions to be drawn therefrom.'" *Charbonnages*, 597 F.2d at 414 (quoting *Pierce v. Ford Motor Co.*, 190 F.2d 910, 915 (4th Cir. 1951), *cert. denied*, 342 U.S. 887 (1951)). When the evidence is viewed in this way, if a fair-minded jury could return a verdict for the non-moving party, summary judgment must be denied. *Anderson*, 477 U.S. at 252. That is exactly the situation as presented here.

ARGUMENT

Plaintiff and Defendants are in agreement that California choice-of-law rules apply in this

case and as such, California substantive law applies to Ms. Jacobson's claims.

I. PLAINTIFF HAS PRODUCED SUFFICIENT EVIDENCE THAT A REASONABLE JURY COULD FIND THAT DEFENDANTS' FAILURE TO WARN PROXIMATELY CAUSED PLAINTIFF'S INJURIES.

Defendants ask the Court to grant summary judgment as to all of Plaintiff's failure-to-warn claims, arguing that Plaintiff cannot establish causation and is barred by the learned intermediary doctrine. (*See* Def. Memo. 3-6.) Defendants' arguments require this Court to draw all inferences in Defendants' favor, and fail on both factual and legal grounds.

California applies the learned intermediary doctrine in products liability cases involving implanted medical devices such as TVT. *See Hufft v. Horowitz*, 4 Cal. App. 4th 8, 23 (1992) (applying learned intermediary rule in case involving penile implant.). Originally developed in the prescription drug context, the learned intermediary doctrine requires that a defendant's warning in certain products liability actions must be communicated to the physician rather than the patient. *See Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467, 1483 (1999).[2] In order for a manufacturer of a drug or device to be absolved of liability, the warning it provides to the physician must be adequate. *See Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89, 98 n.5 (2008); *see also Stewart v. Union Carbide Corp.*, 190 Cal. App. 4th 23, 29-30 (2010) (the warning provided to a sophisticated user [tantamount to the physician in a learned intermediary case] was inadequate and, therefore, could not absolve the defendant manufacturer of liability where neither the sophisticated user nor the manufacturer warned the plaintiff of the product at issue.) ("If both Union Carbide and the sophisticated intermediary failed to give warnings, that should not absolve Union Carbide of responsibility.") *Id*. at 30.

[2] "In the case of prescription drugs and implants, the physician stands in the shoes of the 'ordinary user' because it is through the physician that a patient learns of the properties and proper use of the drug or implant. Thus, the duty to warn in these cases runs to the physician not the patient."

Ms. Jacobson may assert failure to warn claims as long as she can establish sufficient facts to show that Defendants either did not warn, or provided inadequate warnings, to her learned intermediary, Dr. Cronbach; and, that the lack of an adequate warning resulted in the patient's injury. *See Singleton v. Eli Lilly Co.*, No. 1:10-cv-02019-AWI-SKO, 2012 WL 2018536, at *3 (E.D. Cal. Jun. 5, 2012). This she can do, and Defendants should not be absolved from liability to Ms. Jacobson on her failure to warn claims, because they: 1) failed to provide Dr. Cronbach with adequate warnings regarding the dangerous qualities of the TVT device, 2) failed to provide legally-required ongoing information about risks and warnings attendant to the TVT device over the course of Dr. Cronbach's use of the TVT product and its complications in Ms. Jacobson; and 3) Ms. Jacobson would not have undergone the TVT procedure had Dr. Cronbach been adequately warned.

First, Defendants' warnings were inadequate under the law. Plaintiff has demonstrated that the warnings contained in the TVT Instructions for Use ("IFU") were inadequate and failed to warn of the appropriate risks. (*See* Ex. C, Gynecare TVT Instructions for Use 11.29.2010 to Present.) According to Plaintiffs' expert, Dr. Bruce Rosenzweig, Defendants' IFU for the TVT device was inadequate in that it did not include all known risks, was inaccurate, and was not updated:

- The IFU fails to inform physicians that patients may require multiple surgeries to treat erosions, that erosions could be severe and untreatable, that patients could endure lifelong severe pain or dyspareunia/painful sex, removing the mesh and revision surgeries can be complicated and challenging for both the patient and physician, and complete removal of the TVT mesh is likely impossible.

- Ethicon failed to include significant risks in its IFU related to the Prolene polypropylene mesh, including potential cytotoxicity, association with tumor formations and that the mesh can degrade, shrink and contract. The IFU also fails to include risks associated with the Prolene mesh, including chronic foreign body reaction, fibrotic bridging, infections/biofilms, fraying/particle loss and roping/curling of the mechanically cut mesh.

- The May, 2015 IFU included a large number of significant updates, including warnings about pain, chronic pain, dyspareunia for the patient and/or her partner, need for multiple surgeries, and the difficulty in removing all or part of the device. These are all risks that Ethicon knew of at the time of launch of the TVT, and should have been included in the IFU since launch.

- In addition, the IFU incorrectly states that the TVT is "tension-free." In reality, it is extremely difficult to correctly "tension" the sling. If placed even slightly too snugly, the tape may cause temporary or permanent lower urinary tract obstruction. This is compounded and the problems increase over time as the TVT contracts, shrinks, and deforms in a woman's body. On the other hand, if the sling is applied too loosely, incontinence will persist. The IFU failed to adequately instruct surgeons on tensioning, and instead offered confusing, and conflicting direction, despite awareness that improper tensioning could lead to serious complications.

- The pre-2015 IFUs are also inadequate in that they downplay complications as "transitory": "Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation." This language is not correct—the complications can be chronic and permanent, not transitory as Ethicon states.

- The IFU also contains inaccurate, false and misleading statements about the degradation of the mesh. The IFU incorrectly states that TVT "is not absorbed, nor is it subject to degradation or weakening by the action of enzymes." This statement is contradicted by Ethicon's own research, internal documents, and scientific literature.

(*See* Ex. D, General Report by Dr. Bruce Rosenzweig, 21-22, 24, 56-80.)[3] *See also* Ex. E, Amended Specific Report by Dr. Bruce Rosenzweig, 13-15.

Many if not most of the items Dr. Rosenzweig identifies as not appearing on the operative IFU are among the symptoms and injuries suffered by Ms. Jacobson. Among them, she experienced 1) chronic pelvic pain; 2) vaginal erosion requiring corrective surgery that may not resolve the symptoms; and 3) pain during intercourse. (*See* Plaintiffs' Statement of Material Facts and associated exhibits.)

[3] A complete discussion of Ethicon's failure to warn physicians is set forth in detail in Dr. Rosenzweig's reports. (*See* Ex. D; Ex. E.)

Second, Defendants were derelict in their duty under California law to continue to provide Dr. Cronbach with warnings concerning the TVT device. Courts in California have held that the duty to warn physicians about the known or knowable hazards of a drug or medical device is ongoing. *See Singleton*, 2012 WL 2018536 at *3 ("The duty to warn is a continuing duty, requiring a manufacturer to notify the medical profession of any side effects of a prescription drug which are subsequently discovered, and is based on the application of scientific knowledge available at the time of manufacture and distribution of the drug."); *see also Valentine*, 68 Cal. App. 4th at 1482 (The court took favorable note of a jury instruction reading: "[A]s more information about adverse effects develop over time, the manufacturer must continue to provide physicians with warnings, at least so long as it is manufacturing, ,and distributing the product.").

Ethicon did not provide Dr. Cronbach with any updated information from 2010 to 2015 regarding the risk of complications that Ms. Jacobson suffered, despite its internal awareness of these risks, thereby failing in its continuing duty to warn. (*See* Ex. D 67-72.) *See also* Ex. F, Defendants Response to Plaintiffs' Interrogatories, 4 ("Ethicon states that any surgeon implanting Ethicon's mesh products would have received the Instructions for Use (IFUs) for such products. Ethicon refers to the IFU Chart attached as Exhibit "A."). *See also* Ex. G, Defendants Fact Sheet for Kristin Jacobson, 3, 14 (chart demonstrating that Dr. Cronbach did not receive any training from Defendants on the TVT after 2010). Further, Ms. Jacobson can show facts to support that Dr. Cronbach received no information or training from Defendants since at least *2001*, other than what was in the IFUs. *See* Ex. G 3, 14 (indicating that Dr. Cronbach did not receive any training on the TVT after 2001). *See* Ex. F 8 (noting that any surgeon would have received the IFU, but that Ethicon does not track professional materials provided to specific

physicians, including Dr. Cronbach). *See* Ex. F 4; Ex. G 3, 14 (failing to identify any individuals who trained or instructed Dr. Cronbach regarding the implantation of or treatment of complications related to the Gynecare TVT). *See* Ex. F 4; Ex. G 3, 14 (confirming only that all surgeons, including Dr. Cronbach, would have received the IFU). Dr. Cronbach cannot have been expected to read a warning she never received. Defendants' failure to provide sufficient warnings in its IFUs, along with its failure to provide any additional information to Dr. Cronbach, despite the fact that Ethicon knew of serious consequences to patients from use of their transvaginal mesh devices including the TVT between 2001[4] and Ms. Jacobson's implant surgery in 2012 is in violation of California law. *See Conte*, 168 Cal. App. 4th at 98, n.5; *see also Singleton*, 2012 WL 2018536 at *3. ("The duty to warn is a continuing duty, requiring a manufacturer to notify the medical profession of any side effects of a prescription drug which are subsequently discovered."); *see also Hufft*, 4 Cal. App. 4th at 23 (applying the learned intermediary analysis to a medical device).

Finally, there is a genuine issue of fact as to proximate causation. Ethicon's failure to provide adequate warnings and continuing updates led directly to Dr. Cronbach's inability to inform Ms. Jacobson fully and properly of the risks she assumed in receiving the TVT device for treatment of her incontinence. Ms. Jacobson discussed with Dr. Cronbach her reasons for seeking SUI treatment—to allow her to engage in more strenuous physical activities, such as long distance running and volleyball with her daughter, and Dr. Cronbach recommended the TVT procedure specifically to address those concerns. (*See* Ex. A LCHB-KLJ-000611.) Dr. Cronbach had a detailed informed consent discussion with Ms. Jacobson, addressing the benefits, alternatives and risks as documented in the IFU. (*See* Ex. A LCHB-KLJ-000700; Ex.

[4] Ethicon admits that Dr. Cronbach had not received any training from Ethicon since at last 2001, and records prior to that date are unavailable. (*See* Ex. G 3, 14.)

C.) These detailed discussions reflected in Dr. Cronbach's clinic notes demonstrate not only that Dr. Cronbach was familiar with the IFU, but also that had she been aware of the additional risks, or aware that these risks were possible complications with the TVT device, she would have relayed these warnings to Ms. Jacobson as part of the informed consent process. (*See* Ex. A LCHB-KLJ-000700, LCHB-KLJ-000775-000777.) Ms. Jacobson testified that she consented to the TVT procedure only because she believed the risks were rare and related to the implant procedure itself. (*See* Ex. B 77:13-82:7.) If she had known of the risks of chronic pelvic pain limiting her activity, pain with sexual intercourse, or that the TVT devices could erode into her surrounding organs requiring corrective surgery, she never would have consented to the TVT implant procedures. (*See* Ex. L, Kristin Jacobson Declaration; Ex. B 76:20-77:5.) Indeed, these risks would have negated her primary reason for undergoing the surgery in the first place. (*See* Ex. A LCHB-KLJ-000611.) A jury could reasonably infer that Dr. Cronbach would not have implanted the TVT without Plaintiff's consent. For these reasons, Dr. Rosenzweig concluded, "to a reasonable degree of medical certainty, Ms. Jacobson suffered injuries that were not disclosed by Ethicon, and the inadequate disclosure of these risks was a substantial factor and/or cause of Ms. Jacobson's injuries." (*See* Ex. E 14.)

As Plaintiffs amply support through a plethora of expert reports, depositions, and other factual averments, questions remain about the lack of adequacy of the warnings that Defendants provided to Dr. Cronbach in its IFU (and other means) and the resulting injuries to Ms. Jacobson. Thus, Defendants' Summary Judgment Motion on failure to warn should be denied.

II. PLAINTIFFS' DESIGN DEFECT—STRICT LIABILITY CLAIM IS VALID UNDER CALIFORNIA LAW

Defendant is correct that California eliminated strict liability for design defect claims in medical devices. *See Garrett v. Howmedica Osteonics Corp.*, 214 Cal. App. 4th 173, 183-85

(2013); *Hufft*, 4 Cal. App. 4th at 11. However, in so doing, courts have made it clear that design defect claims continue to survive for failure to warn even in strict liability. *See Garrett*, 214 Cal. App. 4th at 183 ("Drug manufacturers [and device makers], however, are *not* exempt from liability for manufacturing defects, failure to warn, and negligence.") (emphasis in original); *see also Carlin v. Superior Court*, 13 Cal. 4th 1104, 1117 (1996). As said previously, under California law, the warning a device manufacturer owes runs to a plaintiff's physician. (*See supra*, 10-11; *see also*, *e.g.*, *Barney v. St. Jude Medical Center, Inc.*, No. C-92-1058-DLJ, 1993 WL 13015619, at *3 (N.D. Cal. Feb. 12, 1993) (applying California law and holding, "[t]he manufacturer of a medicine or medical device satisfies its duty to provide an appropriate warning about the product's risks when it informs the patient's physicians of those risks."). The required warning must be sufficient to provide notice of any defect that a manufacturer knew or should have known existed. *See Garrett*, 214 Cal. App. 4th at 182 ("Under the negligence standard as reflected in comment k to section 402A of the Restatement Second of Torts...a manufacturer is liable for a design defect only if it failed to warn of a defect that it either knew or should have known existed.").

The Plaintiffs have already argued at length above that Ms. Jacobson's implanting physician, Dr. Cronbach, was not put on notice of several major flaws with the TVT device that Defendants either knew or should have known about. In particular, the Plaintiffs can raise questions of fact regarding Ethicon's failure to warn Dr. Cronbach either through training, IFUs, or other materials regarding several known hazards with the TVT device. (*See* above.) Thus, the Plaintiffs raise questions of fact regarding design defects in the TVT device. Their design defect claims based on Defendants' failure to provide adequate warnings to Dr. Cronbach are not precluded by California law, and Ethicon's Motion for Summary Judgment must be denied on

this ground as well.

III. PLAINTIFFS' MANUFACTURING DEFECT CLAIM IS VALID UNDER CALIFORNIA LAW AND SHOULD NOT BE DISMISSED

To bring a strict liability claim for a manufacturing defect in California, a plaintiff must show that the product in question "differs from the manufacturer's intended result or from other ostensibly identical units of the same product line." *See Garrett*, 214 Cal. App. 4th at 190. In its Summary Judgment Brief, Defendants focus solely on the requirement that a product must differ from others in its product line to constitute a manufacturing defect. *See* Def. Mem. 7-8. This, Plaintiffs admittedly cannot do.

However, Plaintiffs' experts can show that the TVT differed from Ethicon's intended result. In its TVT marketing, Ethicon claims that "most complications are minor and are avoidable with adherence to procedural technique and instructions for use." (*See* Ex. D 59.) However, even with proper technique and adherence to the IFU, the TVT device implanted in Ms. Jacobson caused a multitude of problems including: chronic and debilitating pain, chronic dyspareunia and sexual dysfunction, vaginal scarring, bladder dysfunction, recurrent urinary or bladder infections, recurrence, the need for corrective surgeries that may not resolve the symptoms, the marked difficulty removing the mesh sling, and that even worse complications may ensue from mesh removal, the difficulties that occurred in treating the worsening of SUI following sling removal, and others. (*See* Ex. E 12-14; Ex. B 113:15-115:4.) Since no reasonable manufacturer would intend for its product not to be the safe cure it advertised—but instead—be the cause of a plethora of debilitating and permanent injuries like the TVT device, Plaintiffs have sufficiently raised questions of fact regarding their strict liability manufacturing

defect claim sufficient to overcome Defendants' Summary Judgment Motion.[5]

IV. DEFENDANTS MISREPRESENT THE APPLICABLE LEGAL STANDARD FOR NEGLIGENCE, NEGLIGENT MISREPRESENTATION, NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS, AND GROSS NEGLIGENCE AND PLAINTIFFS HAVE PROFERRED THE REQUISITE EXPERT EVIDENCE TO SURVIVE SUMMARY JUDGMENT

Contrary to Defendants' assertions, Plaintiffs' negligence based claims cannot be dismissed based on this Court's disposition of Plaintiffs' failure to warn claims. Defendants attempt to assert the same arguments which this Court has already disposed of in *Sanchez v. Boston Scientific, Corp.*, 1738 F. Supp. 3d 727, 737 (S.D. W. Va. 2014). As this Court has previously ruled, "medical device manufacturers may be liable for design defects under the ordinary principles of negligence" in California. *Id.* Thus, the Court can swiftly reject Defendants' arguments on this point.

In California, negligence theories survive summary judgment even when courts dismiss failure to warn claims for lacking evidence of causation under the learned intermediary doctrine. *Tucker v. Wright Med. Tech., Inc.*, No. 11-cv-03086, 2013 WL 1149717, at *10, 16 (N.D. Cal. Mar. 19, 2013) (granting defendant's motion for summary judgment on plaintiffs' strict liability and negligent failure to warn claim, because there was no evidence the implanting physician read the defendants' warning, but denying defendant's motion for summary judgment on plaintiff's negligence claim under California law); *Valentine*, 68 Cal. App. 4th at 1487 n. 15 (explaining

[5] In light of the Court's consistent rulings across these pelvic mesh MDLs as to manufacturing defect claims, Plaintiffs does not intend to pursue a separate claim for "manufacturing defect," as such claim has been construed by this Court (not manufactured in accordance with design, or departure from manufacturer's design specifications). However, Plaintiffs do intend to present evidence that Defendants' manufacturing process, and the raw materials used in the manufacture of the TVT products, resulted in defects in the product, and in support of Plaintiffs' negligence, failure to warn, and punitive damages claims, which is consistent with the Court's prior rulings. By agreeing not to pursue a "manufacturing defect" claim as it has been construed by this Court, Plaintiffs do not forego, waive or agree that any evidence relating to Defendants' manufacturing process and raw materials are restricted in any way.

that a negligent design claim can stands alone without a failure to warn claim in California because the two causes of action involve separate rights and duties). *Tucker* illustrates that California's learned intermediary doctrine does not bar every cause of action against a manufacturer of medical devices. 2013 WL 1149717. In that case, the plaintiff brought a products liability action against the manufacturer of hip implants after sustaining injuries resulting from the implantation of a defective hip replacement. *Id.* at *1-2. But, "there [was] no evidence that [the plaintiff's doctor] read the warnings provided by Defendant." *Id.* at *16. Applying *Motus I* and *Motus II*, that court granted summary judgment on the plaintiff's strict liability and negligent failure to warn claims because there was no evidence that the defective warnings caused the plaintiff's injuries. *Id.* However, the learned intermediary doctrine did not bar the plaintiff's negligent design claim, and that court denied summary judgment on that claim. *Id.* at *10. *Tucker* provides that negligence-based claims survive summary judgment even when the learned intermediary doctrine bars his or her strict liability and negligent failure to warn claims.

Here, even if the Court determines the learned intermediary doctrine bars Plaintiff's failure to warn claims, the following negligence based claims—pleaded in Plaintiffs' Short Form Complaint and Master Complaint—under California's substantive law survive summary judgment under *Tucker* and *Saavedra*:

- **Negligence**. *Friedman v. Merck & Co.*, 107 Cal. App. 4th 454, 463 (2003);
- **Negligent Design**. *Chavez v. Glock, Inc.*, 207 Cal. App. 4th 1283, 1305 (2012);
- **Negligent Failure to Test**. *Post v. Alameda Amusement Co.*, 117 Cal. App. 2d 588, 590 (1953);
- **Negligent Undertaking of the Duty to Train**. *Artiglio v. Corning Inc.*, 18 Cal. 4th 604, 613-14 (1998); *Paz v. State of California*, 22 Cal. 4th 550, 559 (2000).

- **Negligent Misrepresentation**. *Apollo Capital Fund, LLC v. Roth Capital Partners, LLC*, 158 Cal. App. 4th 226, 243-44 (2007).

Thus, summary judgment is inappropriate on Plaintiffs' negligence based claims because California's learned intermediary doctrine does not bar those claims.

Plaintiffs have offered substantial evidence that Defendants breached their duty and did not act as a reasonable medical device manufacturer, including failing to warn physicians and patients of known risks. (*See* Sections I-II, *supra*.) Dr. Rosenzweig and Plaintiffs' other experts have offered opinions that Defendants negligently designed the TVT. As Dr. Rosenzweig summarized in his report:

> Ethicon has marketed and sold the TVT despite the fact that it is contains numerous characteristics that make it unsuitable for implantation in a woman's vagina. These characteristics include the following: (1) degradation of the mesh; (2) chronic foreign body reaction; (3) fraying, sharp edges and particle loss; (4) Infections and Bio-films; (5) roping and curling of the mesh; (6) loss of pore size with tension; (7) fibrotic bridging leading to scar plate formation and mesh encapsulation; and (8) shrinkage/contraction of the encapsulated mesh.

(See Ex. D 98.) *See also* Ex. J, General Report by Dr. Uwe Klinge, 1-4 (concluding that: (1) the Prolene mesh used in Ethicon's TVT products is designed in such a way that unnecessarily caused greater inflammatory response and greater foreign body reaction in women's pelvic tissues leading to harmful complications in some patients, (2) these materials were inadequately tested and studied before sold; and (3) were not adequately designed to be safely implanted in a woman's pelvis for the rest of her life). *See also* Ex. K, General Report by Dr. Daniel Elliott, 5 (concluding that the TVT is defectively designed in multiple ways).

Plaintiffs have also offered expert testimony that Defendants engaged in extreme or outrageous conduct, including but not limited to: choosing not to inform physicians and patients

of life-altering risks and debilitating complications that Ethicon knew to be associated with the TVT device. (*See* Ex. D 96-98; Ex. J 9, 31, 33; Ex. K 30-37; Ex. I, General Report by Dr. Vladimir Iakovlev, 10.) Ethicon recklessly marketed and sold an untested, defective, and dangerous product to be permanently implanted in the vaginas of millions of women, knowing it could cause devastating impacts on their lifestyles, interference with their intimate relationships with their spouses, chronic pain, and an inability to engage in the activities that make life worth living. (*See* Ex. D 96-98; Ex. J 9, 31, 33; Ex. K 30-37; Ex. I 10.) It is not as though these products were designed to treat cancer, or some other life-altering condition that might possibly justify the tremendous risks and complications—the TVT was sold to treat SUI, a relatively minor and inconvenient condition. (*See* Ex. D 59.) As Plaintiffs' experts conclude, the TVT never should have been placed in Ms. Jacobson, or millions of other women just like her. (*See generally* Ex. D; Ex. J; Ex. K; Ex. I.) Defendants Motion for Summary Judgment on this point should therefore be denied.

V. PLAINTIFFS HAVE ESTABLISHED ALL ELEMENTS OF THEIR FRAUD AND FRADULENT CONCEALMENT CLAIMS

Plaintiffs have demonstrated all elements of their remaining fraud and fraudulent concealment claims. First, as discussed above, Defendants' warnings regarding the TVT device were inadequate. Second, Plaintiff has demonstrated that: 1) Ethicon did conceal, falsely represent, and did not disclose the true risks of their TVT device; 2) Defendants did so knowingly; 3) intended to induce reliance of patients such as Ms. Jacobson (through her physician); 4) Ms. Jacobson relied on these representations (made to her physician) in obtaining adequate and accurate informed consent related to the TVT device; and 5) that Ms. Jacobson suffered injuries as a result. (*See* Ex. E 12-13; Ex. K 23-24.) Defendants' Motion for Summary Judgment on these claims must therefore fail.

VI. PLAINTIFFS ARE ENTITLED TO SEEK REMEDIES UNDER CALIFORNIA'S UNFAIR COMPETITION LAW ("UCL")

It is by no means clear that even in cases involving prescription drugs or medical devices, that UCL claims cannot be brought directly by plaintiffs. For example, the court in *In re Vioxx Class Cases*, 180 Cal. App. 4th 116, 129 (Cal. App. 2, 2009) was asked to consider class certification in the matter before it but, in so doing, accepted without comment that plaintiffs properly brought their own CLRA and UCL claims against a manufacturer of a prescription drug.). Hence, it is entirely appropriate that Ms. Jacobson brought UCL claims on her own. It is just as clear that she has sufficient facts to show that she actually relied on Defendants to provide materials to her (through her physician) that were adequate for her to make an informed consent prior to undergoing implantation of the TVT devices. (*See* Ex. B 79:21-82:7.) As argued at length herein, these were warnings that Defendant failed to provide adequately, leading to Ms. Jacobson's injuries set forth herein.

VII. PLAINTIFFS' CLAIMS FOR UNJUST ENRICHMENT ARE VALID UNDER CALIFORNIA LAW AND SHOULD NOT BE DISMISSED

Under California law "[u]njust enrichment…is synonymous with restitution." *Dinosaur Dev., Inc. v. White*, 216 Cal. App. 3d 1310, 1314 (1989). "There are several potential bases for a cause of action seeking restitution…restitution may be awarded where the defendant obtained a benefit from the plaintiff by fraud, duress, conversion, or similar conduct. In such cases, the plaintiff may choose not to sue in tort, but instead to seek restitution on a quasi-contract theory.... [Citations.] In such cases, where appropriate, the law will imply a contract (or rather, a quasi-contract), without regard to the parties' intent, in order to avoid unjust enrichment." *Durell v. Sharp Healthcare*, 183 Cal. App. 4th 1350, 1370 (2010) (citing *McBride v. Boughton*, 123 Cal. App. 4th 379, 388 (2004) (fn. omitted)).

In *Astiana*, the very case cited by Defendants, the Court upheld plaintiff's restitution

claim based upon quasi-contract because the plaintiff adequately alleged that the defendant's misleading labels duped the plaintiff into purchasing a product. *Astiana v. Hain Celestial Group, Inc.*, 783 F.3d 753, 762 (9th Cir. 2015). *See also Romero v. Flowers Bakeries, LLC*, Case No. 14-cv-05189-BLF, 2015 WL 2125004, *9 (N. D. Cal. May 6, 2015). Court held that allegations that the defendant enticed the plaintiff to purchase products through misleading labels stated a claim for quasi-contract). Plaintiffs' Long Form Master Complaint alleges very specifically their Unjust Enrichment claims. (*See* Ex. H, Ethicon Long Form Complaint, 55-56.) Therefore, dismissal of Plaintiffs' Unjust Enrichment claims at this juncture would be improper under California law.

CONCLUSION

For all the reasons set forth herein, Ethicon's Partial Motion for Summary Judgment should be denied.

Dated: October 25, 2018

Respectfully submitted,

By: */s/ Wendy R. Fleishman*

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CERTIFICATE OF SERVICE

I hereby certify that on October 25, 2018, I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: October 25, 2018

/s/ Wendy R. Fleishman
Wendy R. Fleishman